

**Modification and Protocol Exceptions Review Checklist**

**Full Board**

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| --- | --- | --- |
| **PI Name:** | | WMed IRB #:  *(for IRB office use only)* |
| **Protocol Title:** | | |
| **Reviewer:** | **Review Date:** Click or tap to enter a date. | |

**Instructions:** This form is intended to be used as a guide for the reviewer to ensure that all required determinations and findings are made and discussed at the IRB meeting. The IRB minutes serve as the official IRB record of final determinations. Reviewers are advised to record details regarding their review in the Comments section to assist in the IRB discussion.

1. **Conflict of Interest**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **Comments** |
| As a reviewer, are you an investigator, consultant, collaborator, or study personnel on the proposed study; do you have a financial interest in the study; or do you have any other conflict of interest with this study? |  |  |  |
| If yes, please do not perform the review and contact the IRB Office at 269.337.4345. | | | |

1. **Review of Modification**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Research Plan:** | **Yes** | **No** | **Comments** |
| 1. Is the purpose of the change summarized on modification request form? |  |  |  |
| 1. Has the initial submission documentation been revised, updated and submitted? |  |  |  |
| 1. Does this change affect the purpose of the study? |  |  |  |
| 1. Does this change affect the procedures of the study? |  |  |  |
| 1. Is there justification for the change(s)? |  |  |  |
| 1. Does this change create the need for the study to be reviewed more frequently? (If yes please note the duration and reasons in the comments section.) |  |  |  |
| 1. Does the change affect the original determination for any of the criteria for approval under 45 CFR 46.111? |  |  |  |
|  |  |  |  |
| 1. **Risk/Benefit:** |  |  |  |
| 1. Does this change affect the risk to subjects? |  |  |  |
| 1. Does this change affect the benefits to subjects or others? |  |  |  |
| 1. Does this change affect the risk/benefit relationship? |  |  |  |
| 1. Does the proposed modification add any procedures, which will unnecessarily expose subjects to risk? |  |  |  |
|  |  |  |  |
| 1. **Consent:** |  |  |  |
| **If the modifications include the addition of new consents, please complete the *“Elements of Consent Review Checklist” for each additional consent.*** |  |  |  |
| 1. Could the change impact the subjects’ willingness to continue participation? |  |  |  |
| 1. Does the change impact any of the elements of consent? (If yes please note the specific elements and reasons in the comments section.) |  |  |  |
| 1. Does the change otherwise provide or alter information that may be important to subjects? |  |  |  |
| 1. Does the change affect the consent process? |  |  |  |
| * 1. If so, is the consent process still appropriate? |  |  |  |
| 1. Is the change reflected in the revised consent document(s), if applicable |  |  |  |
| 1. Should subjects be re-consented? |  |  |  |
| * 1. Should **all** subjects be re-consented? |  |  |  |
| * 1. Should subjects **still active** in the research be re-consented? |  |  |  |
| * 1. Has the PI provided an adequate plan for re-consenting subjects already enrolled? |  |  |  |
|  |  |  |  |
| 1. **Other Concerns:** |  |  |  |
| 1. Does the change affect the recruitment process? |  |  |  |
| * 1. If so, is the recruitment process still appropriate? |  |  |  |
| 1. Does the change require a revised data safety plan? |  |  |  |
| 1. Does the change affect the privacy or confidentiality of subjects? |  |  |  |
| 1. If so, are the procedures to protect privacy and confidentiality still appropriate |  |  |  |
| 1. Does the change include the addition of any vulnerable populations? |  |  |  |
| * 1. If so, are the populations appropriately safeguarded? If the change includes the addition of *Children, Pregnant Women, Fetuses and Neonates or Prisoners please fill out the appropriate Review Checklist Supplement.* |  |  |  |
| 1. Does the change affect the protection of vulnerable subjects? |  |  |  |
| 1. If so, are the protections for vulnerable subjects still adequate? |  |  |  |

1. **Regulatory Criteria for Approval (Section 111 Criteria)**

The following information is designed to assist the reviewer in determining that the federally required criteria for IRB approval codified at 45 CFR Part 46.111 and FDA regulations have not changed due to this modification.

Please note and comment below as to whether the following elements continue to be met**:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **NA** |
| 1. Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. |  |  |  |
| 1. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. |  |  |  |
| 1. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. |  |  |  |
| 1. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by [§46.116](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116#46.116). (or has previously been waived by the IRB) |  |  |  |
| 1. Informed consent will be appropriately documented, in accordance with, and to the extent required by [§46.117](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117#46.117). (or has previously been waived by the IRB) |  |  |  |
| 1. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. |  |  |  |
| 1. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. |  |  |  |
| 1. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. |  |  |  |

**Comments:**

1. **Protocol Exceptions**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **Comments** |
| 1. Is there any increase of harm to subjects as a result of the exception? |  |  |  |
| 1. Will the exception impact the integrity of the data? |  |  |  |
| 1. If so, please explain how. |  |  |  |

1. **Determinations** *(See Section 7.6 of the WMed HRPP and IRB Handbook for information on IRB actions)*

**Recommended IRB Action** *(check one)***:**

Approve as submitted

Approve with conditions

Partially Approve

Defer

Disapprove

|  |  |
| --- | --- |
| Please list any changes, modifications, or clarifications required. If the recommendation is for the research is to be deferred or disapproved, please also provide a brief explanation. | |
|  | |
| **Signed** | **Dated** |

**NOTE:** Non-substantive issues include:

1. Confirmation of specific assumptions or understandings on the part of the IRB regarding how the research will be conducted (e.g., confirmation that the research excludes children);
2. Submission of additional documentation (e.g., certificate of ethics training);
3. Precise language changes to protocol or informed consent documents; or
4. Substantive changes to protocol or informed consent documents along with clearly stated parameters that the changes must satisfy.